INSTITUTE: Clinical Center

STUDY NUMBER: 05-CC-0216 PRINCIPAL INVESTIGATORS: Margaret Bevans R.N., Ph.D.

STUDY TITLE: Prospective Assessment of Functional Status, Psychosocial Adjustment, Health Related Quality of Life and the Symptom Experience in Patients Treated with Allogeneic Hematopoietic Stem Cell Transplantation

Continuing Review Approved by the IRB on 04/07/09
Amendment Approved by the IRB on 09/22/09 (G) Date Posted to Web: 10/15/09
Standard

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

Why is this research being done?

The therapies used to treat your illness have many side effects. There is a lot of information on how to improve the physical side effects, such as nausea and vomiting, but there is less known about how this treatment and its side effects impact your life. For example, how does the transplant affect your relationships with others, your job, your energy, and even your happiness?

This study will look at many areas of your life that may be affected by the stem cell transplant. We hope to learn what areas are affected as patients get back to their normal activities. We hope to be able to provide this information to patients and families prior to making decisions about having a transplant. In addition, we may be able to improve services to address these areas and help patients and families with their recovery.

Why are you being invited to participate?
We are evaluating the quality of life of patients who have undergone a stem cell transplant three or more years ago. This study is a companion to the study where you are followed by the transplant team with usual medical care such as blood draws. Your choice to participate in this study will not affect your participation in any other study at the NIH. This study is separate and optional.

How many people will take part in this research study?
300 research subjects will participate in this study.

How long will you take part in this research study?
This study involves completing a series of questionnaires once a year at a time close to your annual transplant follow-up appointment for a period not to exceed 10 years.

What do we do to decide if you are eligible for this research study?
We will ask you a series of questions to determine your eligibility for the study. You must be at least 18 years of age and speak and write English or Spanish to participate.

What procedures, drugs or other treatments are involved in this research study?
If you agree to participate, you will be asked to complete a series of questionnaires. Each question/statement has a range of answers for you to choose. Completing the questionnaires takes between 45 - 60 minutes. You will be asked to complete the questionnaires every year when you are normally scheduled for follow-up with your doctors at the NIH. It is important for you to complete the surveys yourself. No special trips to the NIH will be required just for this study.

If you are not coming to the NIH for your follow-up we will have you complete the survey and return it to us by mail. We will notify you by phone or email that the surveys are being mailed. We will send you specific instructions and pre-paid mailing materials for the return. If we do not receive the surveys back within two weeks of mailing them to you we will contact you by phone to make sure you received them and to answer any questions you might have.

What are the risks and discomforts of this research study?
There are no known risks to completing these questionnaires. The questionnaires will be completed using pen and paper and should take approximately 45 - 60 minutes. We will provide you with privacy during completion while at the NIH. The questionnaires ask a variety of questions about your life and how you feel. Some of the questions may cause anxiety or emotional upset. At any time if you feel concerned about how things are going with this study, please inform the research team. Resources are available in our organization to help with a variety of issues.

Are there any benefits to you if you take part in this research study?
This study will have no direct benefit to you, however, the information provided through this research will help us better understand how treatments such as transplantation affect a person's life. This information may be of future value in helping other patients who choose to undergo a transplant.

What other choices do you have?
You may choose not to participate in this research study. If you choose to not participate or withdraw from this quality of life study there will be no negative effects on your medical care at the NIH.

Are there reasons that your research participation may end early?
Your participation would end early if you decided to withdraw from the study.

What will happen when the research study is over?
You will be notified prior to your final questionnaire completion that your participation is ending and the study is completing its data collection phase.

Will your clinical and test results be shared with you?
There are no clinical tests associated with the participation in this study. If the study investigators determine a questionnaire response does require clinical intervention you will be contacted to clarify and suggest further action.

Will the results of this research study be shared with you?
If you so desire, summary results from this study can be sent to you upon its completion. Please notify the research team if you are interested in receiving this information.

Will any of your blood, tissue or other samples be stored and used for research in the future?
Your information will be stored in encrypted, password protected computer files. Only authorized personnel will have access to these files. The information you provide us will not be routinely shared with anyone, and it will be coded to provide confidentiality. After the study is over, information identifying you personally will be removed and your information will be identifiable only by a number. Only the data identified with the number will remain available for future research studies and analysis.

Will you receive any compensation (money or other) for taking part in this research study?
There is no compensation associated with participation in this study.

Do any of the researchers or the NIH have financial interests related to this research study?
None of the investigators have a financial interest in the study.

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Margaret Bevans, R.N., Ph.D., Building 10, Room 2B13, office (301) 402-9383. Other researchers you may call are: Sandra Mitchell, CRNP, Ph.D., Building 10, Room 2B11, Telephone: (301) 402-0616.

You may also call the Clinical Center Patient Representative at (301) 496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/Legal Representative _____ Date _____

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.
(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/Guardian _____ Date _____

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian _____ Date _____

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM APRIL 7, 2009 THROUGH APRIL 6, 2010.

Signature of Investigator _____ Date _____ Signature of Witness _____ Date _____